DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

May 27, 2015

Miromatrix Medical Incorporated
% Miriam Provost, Ph.D.
Biologics Consulting Group Incorporated
400 North Washington Street, Suite 100
Alexandria, Virginia 22314

Re: K150341
Trade/Device Name: Miromatrix Biological Mesh RS
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: OXH
Dated: February 9, 2015
Received: February 11, 2015

Dear Dr. Provost:

This letter corrects our substantially equivalent letter of May 12, 2015.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply

with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150341

Device Name
Miromatrix Biological Mesh RS

Indications for Use *(Describe)*
The Miromatrix Biological Mesh RS is for implantation to reinforce soft tissue where weakness exists in patients requiring soft tissue repair or reinforcement in plastic and reconstructive surgery.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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In accordance with 21 CFR 807.87(h) and (21 CFR 807.92) the 510(k) Summary for the Miromatrix Biological Mesh RS is provided below.

Device Common Name:	Surgical Mesh
Device Trade Name:	Miromatrix Biological Mesh RS
Applicant:	Miromatrix Medical, Inc. 18683 Bearpath Trail Eden Prairie, MN 55347
Contact:	Jeff Ross VP Product Development Miromatrix Medical, Inc. Phone: 763-458-8801 Email: jross@miromatrix.com
Date Prepared:	February 9, 2015
Classification Regulation:	21 CFR 878.3300, Class II
Panel:	General and Plastic Surgery
Product Code:	OXH
Predicate Device:	Miromatrix Biological Mesh (K134033)

Indication for Use:

The Miromatrix Biological Mesh RS is for implantation to reinforce soft tissue where weakness exists in patients requiring soft tissue repair or reinforcement in plastic and reconstructive surgery.

Device Description:

The Miromatrix Biological Mesh RS is an implantable, animal-sourced, acellular surgical mesh that is derived from porcine liver tissue. The liver tissue undergoes perfusion decellularization and the resulting mesh is comprised primarily of collagen type I. The device is intended to function as a surgical mesh for soft tissue repair while providing a scaffold for tissue incorporation. The device is terminally sterilized in its packaging and is hydrated, moist and flexible when its packaging is opened. The mesh is available in sizes ranging from 1 cm x 2 cm to 20 cm x 30 cm, and may be trimmed or cut as required before being sutured to the surgical site.

The Miromatrix Biological Mesh RS is identical in materials and design to the predicate Miromatrix Biological Mesh (K134033). The design is consistent with other FDA-cleared meshes indicated for use for plastic and reconstructive surgery. There is no change to the fundamental scientific technology and, thus, no new questions of safety or effectiveness compared to the predicate device.

Performance Data:

Because the materials and design of the subject Miromatrix Biological Mesh RS are identical to that of the predicate Miromatrix Biological Mesh (K134033), no new biocompatibility, bench or animal testing is required to support the substantial equivalence to the predicate device.

Device Comparison Table:

	Proposed Device	**Predicate Device**
510(k) Number	K150341	K134033
Applicant	Miromatrix Medical Inc.	Miromatrix Medical Inc.
Device Name	Miromatrix Biological Mesh RS	Miromatrix Biological Mesh
Classification Regulation	21 CFR 888.3300	same
Product Code	OXH	FTM
Indication	The Miromatrix Biological Mesh RS is for implantation to reinforce soft tissue where weakness exists in patients requiring soft tissue repair or reinforcement in plastic and reconstructive surgery.	The Miromatrix Biological Mesh is intended to be implanted to reinforce soft tissue.
Design	Single-layer biologic mesh that is derived from porcine liver tissue. The mesh is acellular and not cross-linked. The mesh provides a scaffold during tissue repair. The mesh is terminally sterilized in its packaging and is hydrated, moist and flexible when its packaging is opened.	same
Sizes	Available in sizes ranging from 1x2cm to 20x30cm. Can be cut to shape.	same
Thickness	0.5-3 mm	same
Tissue Origin	porcine	same
Single Use	Yes	Yes
Sterile	Yes	Yes

Substantial Equivalence Conclusion:

The Miromatrix Biological Mesh RS is identical in materials and design to the predicate Miromatrix Biological Mesh (K134033). The design is consistent with other FDA-cleared meshes indicated for use for plastic and reconstructive surgery. There is no change to the fundamental scientific technology and, thus, no new questions of safety or effectiveness compared to the predicate device.

The proposed indication for the subject device is different than that of the predicate device. However, the use of the mesh for plastic and reconstructive surgery does not raise any new safety or effectiveness questions compared to its previous indication for reinforcement of soft tissue. Furthermore, similar to other surgical meshes that have been cleared for plastic and reconstructive surgery (e.g., SIS Plastic Surgery Mesh, K034039), the Miromatrix Biological Mesh RS does not provide full mechanical support when used for this indication. Therefore, this proposed indication does not represent a new intended use.

In conclusion, based on identical materials and design, similar indications, and the same intended use, the subject Miromatrix Biological Mesh RS is substantially equivalent to the predicate device, the Miromatrix Biological Mesh (K134033).